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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,763	12/21/2001	John Robert Tagg	512585-2001	5286

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Frommer Lawrence & Haug
745 Fifth Avenue
New York, NY 10151

EXAMINER

MELLER, MICHAEL V

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 06/03/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/913,763

Applicant(s)

TAGG ET AL.

Examiner

Michael V. Meller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 24-26 and 41-46 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-23, 27-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

The restriction requirement of record is maintained for the reasons of record.

Claims 24-26, 41-46 remain withdrawn from further consideration by the examiner.

This application contains claims 24-26 and 41-46 which are drawn to an invention nonelected with traverse in Paper No. 11. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 1, 2, 4-23 and 27-40 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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The rejection is under 35 USC 112, first paragraph. The claims are drawn to a protein other than the only protein which applicant have clearly described that they were in possession of at the time the invention was made, i.e. SEQ ID 3. Applicant have argued that the ordinary skilled person would have been able to through routine experimentation make the proper substitutions or deletions to SEQ ID NO 3 to yield the other proteins claimed but this is simply not true. There is no evidence on the record that applicant was in clear possession of a protein other than SEQ ID NO 3. One of ordinary skill in the art would have had no idea which amino acids to substitute, delete, etc. There is simply not any guidance on how to do this in the specification and no evidence of possession of any protein other than SEQ ID NO 3.

Claims 1, 5-23 and 27-29, 33-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant has now amended claim 1 to use the word, "obtainable". Either the protein is obtainable from the microorganism or it is not. Such language is vague and indefinite.

Applicant argues that the examiner argued that when both K12 and K30 strains are used that both salivaricin A and B are produced, but it is clear from the bottom of page 16 of the specification that one only has to select from K12 and K30 strains, not necessarily use both of them to produce both salivaricin A and B. Thus, applicants arguments are moot.

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It is still noted that the phrase "or an antibacterial variant of the antibacterial protein, which variant has greater than 80 % amino acid sequence identity with said protein" is vague and indefinite for the reasons of record. Applicant did not comment on this rejection but the rejection is maintained for the reasons of record.

Claim Rejections - 35 USC § 102

Claims 1, 2, 4-15, 21-23, 27-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Caufield et al.

Applicant's comments and declaration are noted but the computer read out is quite clear that more than 80% of the sequence is matched. The reference meets the claims. Applicant has obviously decided to create their own system or algorithm. The computer readout is an accurate determination of the exact comparison of the prior art amino acid sequence and that of Caufield.

Claims 1, 2, 4-11, 13, 21-23, 27-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Ross et al., Tagg, Sanders Jr. et al. , Matsushiro or Kawai et al.

Applicant argues that the references disclose different activity than what is claimed but the activity is inherent to the microorganism. The same microorganism is used thus the same protein is obtained. The rejection is based on inherency and it would be inherent that the same protein is produced.

Claim Rejections - 35 USC § 103

Claims 1, 2, 4-23, 27-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caufield et al.

Applicant argues what is in the above discussion of the 35 USC 102 rejection using Caufield, thus the same response is used here again.

Claims 1, 2, 4-23 and 27-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ross et al., Tagg., Sanders Jr. et al. , Matsushiro or Kawai et al.

Applicant argues what is in the above discussion of the 35 USC 102 rejection using the references, thus the same response is used here again.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 703-308-4230. The examiner can normally be reached on Monday thru Friday: 9:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A handwritten signature in black ink, appearing to read 'M. Meller', with a long horizontal flourish extending to the right.

Michael V. Meller
Primary Examiner
Art Unit 1654

MVM
May 22, 2003